PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Gerald Wynn HALLWORTH

Serial No.: 09/651,083

Filed: August 30, 2000

Group Art Unit: 1615

Examiner: A. Pulliam

#11
HKD
4.24.02

For: INHALATION COMPOSITION CONTAINING LACTOSE PELLETS

REQUEST FOR RECONSIDERATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Official Action of January 14, 2002, in connection with the above-identified application.

In addition, Applicants submit herewith a Notice of Appeal from the Final Rejection and also submit the required Appeal fee.

Applicants acknowledge with appreciation the courtesy of the interview granted the undersigned attorney by Assistant Examiner Pulliam and Primary Examiner Kishore at which time the outstanding rejections were discussed but no agreement was reached as reflected in the Examiner Interview Summary Record.

As noted in the Examiner Interview Summary Record, it was emphasized at the interview by the undersigned attorney that the requirements of 35 U.S.C. 102(b) were not met by the Hartley et al reference and claim 18 is not anticipated by Hartley et al. The Examiners maintained that there is an implicit teaching in the reference which anticipates the claimed invention making specific reference at the interview to column 1, lines 52-60 and column 4, lines 23-38 of Hartley et al, neither of which specify lactose nor that it is in pellet form as required by claim 18.

The undersigned attorney also pointed out at the interview that the limitations for the dependent claims, such as claim 19, were clearly not suggested by the Hartley et al. reference and the dependent claims, including claim 19, were clearly allowable. As noted in the Examiner Interview Summary Record, a careful evaluation will be made [by

the Examiners] to determine the allowability of this claim, i.e., claim 19. The rejection of claim 18 under 35 U.S.C. 102(b) as anticipated by Hartley et al has been carefully considered but is most respectfully traversed.

The Official Action states that Hartley et al teaches that according to a specific feature of their invention, sodium cromoglycate, having an effective particle size of from 0.01 to 10 microns, is useful for mixing with lactose of particle size from 30 to 80 microns in order to produce a composition suitable for inhalation. The Official Action refers to column 3, lines 56-65 of the Hartley et al reference.

Applicants have also considered the comments in the Official Action with respect to the Hartley et al reference, especially at column 1, lines 51-56 which points out that for the purposes of the Hartley et al. invention there is no distinction between a single particle of given size and an agglomerate of the same size which is composed of finer individual particles. The term "effective particle size" is therefore used in Hartley et al. to denote the apparent particle size of the body without distinction as to the number of individual particles which go to make up that body. Clearly, one of ordinary skill in the art would appreciate that the "particles" may either be a single particle of a specific size or an agglomerate of the same size which is composed of finer individual particles. Hartley et al describe the solid pharmaceutical acceptable water-soluble carrier as having a particle size of from 30 to 80 microns and that it is especially preferred that the composition is substantially free of particles in the effective size range 11 to 29 microns.

At column 2 of the patent, line 50, it is noted that a particularly preferred diluent or carrier is crystalline lactose. The specification contains two specific examples, examples 1 and 2, as set forth beginning at the bottom of column 3 of the patent. Example 1 describes the use of commercially available ground crystalline lactose in the sentence bridging columns 3 and 4 of the patent. However, there is no indication of whether the ground crystalline lactose is a single particle or an agglomeration, However, it is noted that the lactose particles have been subjected to grinding. The ground particles were then passed through an air classifier to restrict the particle size and the particles were then sieved through a sieve having a mesh aperture of 63 microns to produce a lactose product which contains the appropriate particle size.

As noted at column 4, line 23, of the Hartley et al reference, compositions containing the desired proportions of the coarse and fine materials were mixed together in a planetary mixer and the mixture then passed through a 30 mesh sieve to remove or break up agglomerated particles. Thus, the reference clearly teaches breaking up any agglomerated particles if any were present or were created after earlier treatment. Clearly, one of ordinary skill in the art would appreciate that the lactose was not present in the form of a pellet in accordance with the present invention.

In this regard, the Examiner's attention is most respectfully directed to page 4 of Applicants' specification which discusses the internal strength or coherence of the lactose pellets of use in the present invention. These may be either hard or soft lactose pellets or a mixture of hard and soft pellets. It is noted that in a preferred embodiment the lactose pellets are soft and contain a low internal coherence. These lactose pellets are friable and have an internal coherence such that the pellets remain substantially intact under conditions of packing, transport, storage and when fluidized within a container in the inhalation device from which it is intended to be disposed, the composition according to the invention, e.g., unit dose container or bulk reservoir may be disrupted into independent microfine lactose particles upon egress into the turbulent airstream within the mouthpiece of the inhaler device. Clearly, the pellet of the present invention is not anticipated by the teachings of Hartley et al as would be fairly interpreted by one of ordinary skill in the art to which the invention pertains.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Applicants most respectfully submit that claim 18 requires that certain claim limitations including a preformed lactose pellet which pellet comprises a plurality of microfine lactose particles. There clearly is no explicit teaching of this limitation in Hartley et al and one of ordinary skill in the art would appreciate that the examples do not inherently contain such a pellet in view of the grinding processing steps in the example. Accordingly, it is most respectfully requested that the rejection under 35 U.S.C. 102(b) be withdrawn.

The rejection of claims 18-39 under 35 U.S.C. 103 as being unpatentable over Hartley et al. (as discussed in the 102(b) rejection) has been carefully considered but is most respectfully traversed.

Applicants again wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

In the Official Action it is admitted that Hartley et al. do not teach that the lactose particles are between 150 and 1500 microns in size. It is then stated that it is the position of the Examiner that the specific size of the lactose particles is a limitation

which would be routinely determined by one of ordinary skill in the art. Furthermore, the determination of a particular size of a lactose pellet is within the skill of the ordinary worker as part of the normal optimization. It is then concluded that additionally the burden is shifted to Applicant to show a finding of unexpected results using specific size of lactose particles. This aspect of the rejection is specifically traversed as is the legal conclusion with respect to Applicants' burden. Applicants most respectfully submit that the rejection is clearly based upon hindsight and that the necessary motivation to modify the teachings of the reference must be found in the prior art and not Applicants' specification. In fact the Official Action has not met its burden of establishing that the claimed invention is prima facie obvious.

In this regard, the Examiner's attention is particularly directed to MPEP §2143.01 at page 2100-124 of the August 2001 edition of the MPEP. As noted therein, a statement that modification of the prior art to meet the claimed invention would have been well within the ordinary skill in the art at the time that the claimed invention was made because the references relied upon teach that all aspects of the claimed invention were individually known in the prior art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Applicants most respectfully submit that the size limitation of claim 19 of 150 to 1000 micrometers is clearly not suggested to one of ordinary skill in the art by the explicit teaching in Hartley et al. of a size of from 30 to 80 microns in order to produce a composition suitable for inhalation. See for example, column 3, lines 63-65 of the reference. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The Examiner's attention is also most respectfully directed to the limitations contained in claim 20 which further claims the composition according to claim 18, wherein at least about 90% by weight of the microfine particles of lactose have a diameter of less than about 15 micrometers. This limitation is not suggested by the Hartley et al reference and there is no motivation which would lead one of ordinary skill in the art to this limitation other than Applicants' specification which may not be used as a teaching reference. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is

impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

This is especially true in view of the teaching at column 1, lines 48-51 of Hartley et al that according to a specific preferred embodiment of the invention the composition is substantially free of particles in the effective size range of 11 to 29 microns. This clearly teaches away from the claim limitation of claim 20 wherein at least 90% by weight of the microfine particles of lactose have a diameter of less than about 15 micrometers.

As noted at page 2 of Applicants' specification, beginning at line 20, the particle size of the "microfine" particles of medicament and lactose should be such as to permit substantially all of the particles to be potentially available for inhalation into the lungs upon administration of the powder composition. Thus, for example, at least 90%, preferably at least 95% by weight of the particles will have a diameter of less than 5 micrometers, preferably in the range of 1 to 10 micrometers, for example, 1 to 5 micrometers. This aspect of the invention is clearly not suggested by Hartley et al. Accordingly, it is most respectfully requested that the rejection of claim 20 be withdrawn.

The limitations of claims 22 and 23 are also clearly not suggested by Hartley et al. Claims 22 and 23 relate to a pharmaceutical powder composition which is contains a soft lactose pellet having a crushing weight of about 50 to 500 mg and claim 23 is limited to a crushing weight of about 50 to 100 mg. Again, there is absolutely no suggestion in the Hartley et al reference art which would lead one of ordinary skill in the art to a pellet having these limitations. As previously noted, this crushing weight is described on page 4, second full paragraph of Applicants' specification. It is noted that the soft lactose pellets with a low internal coherence represent a preferred aspect of the invention. As noted, these lactose pellets are friable and have an internal coherence such that the pellets remain substantially intact under conditions of packaging, transport, storage and when fluidized within a container in the inhalation device for which it is intended to dispense the composition according to the invention, i.e., unit

dose container a bulk reservoir and yet may be distributed into independent microfine lactose particles upon egress in the turbulent airstream within the mouthpiece of the inhaler device. There is no recognition of this advantage in Hartley et al reference including no motivation to arrive at the claimed subject matter with these characteristics. Obvious to try is not the standard of obviousness under 35 USC 103.

Applicants note that the processes set forth in claims 29 and 32 are not suggested by the prior art. Again, there is no discussion of the formation of a pellet or of coating the lactose pellets with a liquid suspension or solution of medicament in the Hartley et al reference. There is no discussion in the reference which would suggest the limitations of these claims from the prior art and Applicants' specification may not be used as a teaching reference and this aspect of the rejection is clearly based upon hindsight. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn. Clearly, for the above reasons claims 18 through 39 are patent over the Hartley et al reference and the rejection should be withdrawn.

In view of the above comments, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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April 15, 2002